UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, *et al.*, *ex rel.* JULIANNE NUNNELLY and MATTHEW SHANKS Plaintiffs, v. REGENERON PHARMACEUTICALS, INC., Defendant.	No. 20-cv-11401-PBS

GOVERNMENT SURREPLY IN OPPOSITION TO
REGENERON'S MOTION TO DISMISS

The Court should deny Regeneron's Motion to Dismiss for the reasons the Government set forth in its Opposition (ECF No. 151). Nothing in Regeneron's Reply (ECF No. 153) changes the analysis. The United States' and the States' Complaints (more than) plausibly allege that Regeneron paid hundreds of millions of dollars to subsidize purchases of Eylea, that those payments were price concessions, and that Regeneron knowingly submitted false ASP reports, excluding those amounts, to inflate the rates at which the government paid for Eylea. Regeneron's credit card subsidies lowered the price of Eylea and also allowed retina practices to profit from hundreds of millions of dollars in cash back on their Eylea credit card purchases. To that latter point, Regeneron asks: "so what?" Reply at 12. The answer is evident. Regeneron had a motive and plan to make Eylea more lucrative for retina practices that Regeneron knew would benefit from lower prices, cash back and other rewards, and higher reimbursement rates resulting from Eylea's falsely inflated ASP reports. By failing to report in ASP what it knew were obvious price concessions, Regeneron inflated reimbursements for Eylea, a top Medicare

expense (over $25 billion between 2012 and 2023), and bilked Medicare and Medicaid, and by extension, the American taxpayer, out of hundreds of millions of dollars.

In its Reply, Regeneron belatedly acknowledges that the plain language of the applicable "regulation begins by declaring that 'a manufacturer must deduct price concessions' in calculating ASP[.]" Reply at 4 (quoting 42 C.F.R. § 414.804(a)(2)(i)). Regeneron provides no persuasive explanation for why the express language at issue ("must deduct price concessions") does not mean exactly what it says. Instead, it argues that the Court should adopt Regeneron's cramped interpretation because the regulation does not explicitly say that a manufacturer "must deduct *all* price concessions[.]" Reply at 5 (emphasis in original). Regeneron similarly argues that the Court can ignore a plain reading of the regulation because CMS did not add specific types of transactions and items to the list of enumerated categories appearing in the statutory language. Given that CMS specifically added the "must deduct price concessions" language to the applicable regulation in 2006, however, the Court need not credit Regeneron's baseless insistence that the regulation "only parroted the statutory list[.]" Reply at 4; 71 Fed. Reg. 48,982, 49,082 (Aug. 22, 2006) (proposed rule for 42 C.F.R. § 414.804(a)(2)(i)); 71 Fed. Reg. 69,624, 69,787 (Dec. 1, 2006) (final rule for 42 C.F.R. § 414.804(a)(2)(i)).

Regeneron concedes, as it must, that "the word 'include' can signal that the list that follows is meant to be illustrative rather than exhaustive." Reply at 5, quoting *Samantar v. Yousuf*, 560 U.S. 305, 317 (2010); *see id.* at n.2 ("[T]he word 'includes' is usually a term of enlargement, and not of limitation[.]") (internal quotation omitted). And that is clearly the meaning of "include" in the regulation at issue here. *See, e.g.,* 71 Fed. Reg. at 49,000 ("As a part of that calculation, manufacturers are to take into account price concessions *such as* . . . .") (emphasis added); 71 Fed. Reg. 69,666 (As a part of that calculation, manufacturers must take

into account price concessions *such as* . . . .). Regeneron's argument that the regulation would need to specifically identify credit card subsidies as price concessions is contrary to the language of the regulation, the preamble, and common sense—the purpose of the regulation and the bona fide service fee ("BFSF") provisions was to ensure that ASP captures price concessions, whatever form they take. That is, price concessions need not be characterized as part of any of the enumerated categories in 42 U.S.C. § 414.804(a)(2)(i)(A)-(E) to be deducted from ASP.

Regeneron proclaims that the government had "no answer" to certain arguments, Reply at 7, while conveniently ignoring the parts of the Opposition that address those very arguments. Contrary to Regeneron's assertion, the Opposition does explain why overfill is not a price concession. Reply at 7; Opp. at 14, n.1. The Opposition does explain why Regeneron's credit card subsidies are distinguishable from shipping fees and other BFSFs. Reply at 2, 11; Opp. at 21, 23.[1] The Opposition does explain that the credit card subsidies were not BFSFs. Reply at 2, 11-12; Opp. at 20-23. The Opposition does explain that Regeneron acted knowingly under the FCA; it does not require the court to "draw manifestly unreasonable inference[s]." Reply at 19; Opp. at 31-37. And the Opposition does explain that Regeneron's scheme caused the submission of false claims at inflated rates. Reply at 15-18; Opp. at 25-31.

In its Reply, Regeneron erroneously asserts for the first time that the 2009 False Claims Act amendments "newly defin[ed] 'claim'" to include a "request or demand . . . for money or property[,]" and that this supposed addition forecloses the government from relying on pre-2009

[1] Regeneron's "Exhibit A" is consistent with the effective regulation: because BFSFs are not price concessions they did not need be reported in ASP prior to the amendment. *See* Reply at 7; Ex. A (stating "[BFSFs] . . . should not be included in the calculation of ASP, because those fees would not ultimately affect the price realized by the manufacturer."). After the amendment, when CMS expanded reportable price concessions, it defined BFSFs to clearly establish what payments qualify as BFSFs and therefore do not constitute reportable price concessions.

case law pertaining to falsity. Reply at 15-16, quoting 31 U.S.C. § 3729(b)(2). But this assertion is incorrect; that language has appeared in the statute *since 1986*. False Claims Amendments Act of 1986, Pub. L. No. 99-562, § 2, 100 Stat. 3153-54 (defining "claim" at 31 U.S.C. § 3729(c) using this same language: "any request or demand . . . for money or property"). Regeneron nonetheless argues that this imagined "narrow[ing]" of the FCA defeats the United States' allegations, and cites inapposite precedent for this alleged post-2009 paradigm shift. Reply at 16. Two of the cited cases do not even reference the definition of a claim under the FCA. For example, Regeneron tries to rely on *United States ex rel. Booker v. Pfizer, Inc.*, 9 F. Supp 3d 34, 53 (D. Mass. 2014), to argue that a false statement "no longer" establishes a false or fraudulent claim. Reply at 17. But the concept expressed in *Booker* that "courts have routinely rejected litigants' attempts to use fraudulent *conduct* to avoid the need to show false *claims*[,]" 9 F. Supp 3d. at 53 (emphasis in original), was not new after the 2009 amendments. Indeed, *Booker* cites in part to a 2003 decision of this Court for that principle. *Id*. (citing *United States ex rel. Franklin v. Parke–Davis, Div. of Warner–Lambert Co.*, No. 96-CV-11651-PBS, 2003 WL 22048255, at *2 (D. Mass. Aug. 22, 2003)). Nor is that concept even relevant here, as the Complaints specifically include representative examples of false claims that are linked to Regeneron's fraudulent conduct. *See, e.g.,* Compl. at ¶ 131. In *United States ex rel. Rodwell v. Excelitas Techs., Corp.*, No. 13-cv-10963-IT, 2015 WL 3766866 (D. Mass. June 16, 2015), which Regeneron also cites for its alleged "Post-2009" sea change, Reply at 16, the court allowed the relator to proceed notwithstanding the fact that the relator was *unable* to identify a particular false claim because "the complaint contain[ed] additional allegations sufficient to show that alleged fraudulent conduct as to specific [goods sold to the government] constituted

material noncompliance with contractual provisions." *Rodwell*, 2015 WL 3766866 at *8.[2] Thus, Regeneron is doubly wrong: there was no paradigm shift, and the government Complaints do identify false claims.

There is accordingly no basis for Regeneron's assertion that the cases cited by the United States in its Opposition would be decided differently now. As set forth in the government Complaints and the Opposition, and consistent with that case law, including *AWP* and *Escobar*, Regeneron caused the submission of false or fraudulent claims to government programs for Eylea at inflated rates. *See, e.g.*, Compl. at §§ 123-131, Opp. at 25-31; *In re Pharm. Indus. Average Wholesale Price Litig.*, 478 F. Supp. 2d 164, 172-173 (D. Mass. 2007) (holding that claims "predicated on an underlying fraudulent pricing scheme" are false).

Regeneron's Reply also contains a number of additional misleading citations. For example, Regeneron cites *Encino Motorcars, LLC v. Navarro*, 584 U.S. 79, 85 (2018) for the proposition that "'The term ['price concession'] is not defined in the statute' or the HHS regulation, 'so 'we give the term its ordinary meaning.'"" Reply at 9-10. A cursory review of *Encino Motorcars* makes clear that the case had *nothing to do* with price concessions, ASP, or any HHS regulations, despite Regeneron's misleading addition of the bracketed ['price concession']. Rather, the Supreme Court was interpreting the meaning of a "salesman" under the Fair Labor Standards Act. *See Encino Motorcars*, 584 U.S. at 85.

[2] Regeneron's citation to *United States ex rel. Grant v. United Airlines Inc.*, 912 F.3d 190 (4th Cir. 2018), Reply at 16, also fails to support its argument. That court held the relator failed to show falsity where the relator's complaint "leaves open the possibility that the government was not billed for and accordingly never paid" for allegedly fraudulent airplane engine repairs, and where the complaint "leaves open the possibility that any fraudulent repairs were remedied prior to government payment." *Grant*, 912 F.3d at 198; *see* Opp. at 30. Again, that is not the situation here, where the Complaints identify specific false claims paid by the government plaintiffs.

Similarly, Regeneron argues that the Medicare claims form certification, requiring physicians "certify that the claim complies with 'all *applicable* Medicare and/or Medicaid laws, regulations, and program instructions[,]" Reply at 17 (quoting CMS Form 1500) (emphasis added by Regeneron), only mandates compliance with laws and regulations that "apply to physicians," whereas the ASP laws and regulations "apply to manufacturers." Reply at 17-18 (citation omitted). No such limiting language appears in the claims form certification, which requires compliance with laws, regulations, and program instructions *applicable to the claim*, regardless of whether the certifying physician was responsible for or aware of violations. *See* Opp. at 28-29; *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 390 (1st Cir. 2011).

And, while Regeneron backs away from accusing the government of attempting to criminalize consumer conduct, the Reply now appears to accuse the government of attempting to restrict merchant use of credit cards. Reply at 13. Once again, Regeneron misses the point: consumers and merchants are free to conduct private business arrangements as they see fit. But manufacturers must deduct price concessions when calculating ASP. When a drug manufacturer whose drug is reimbursed by Medicare Part B provides a price concession, that price concession must be included in ASP, whatever form it takes.

Finally, in its Reply, Regeneron asserts an incorrect interpretation of the Texas Medicaid Fraud Prevention Act ("TMFPA"). Regeneron ignores the plain language of the unlawful acts pled under the TMFPA in this case, none of which require presentment of a false claim to establish liability. *See* Tex. Hum. Res. Code §§ 36.002(1), (2) & (4)(B). Additionally, Regeneron fails to recognize that federal courts in two cases cited by the Government explained that the scope of the TMFPA can be broader than that of the FCA and does not have to be tied to the Medicaid claims

submission process. ECF No. 151 at 48 (citing *United States ex rel. Govindarajan v. Dental Health Progs., Inc.*, No. 3:18-cv-00463-E, 2020 WL 3064712, at *7 (N.D. Tex. June 8, 2020) and *United States ex rel. Patel v. Catholic Health Initiatives*, 312 F. Supp. 3d 584, 607 (S.D. Tex. 2018), *aff'd sub nom*. *United States ex rel. Patel v. Catholic Health Initiatives*, 792 Fed. Appx. 296 (5th Cir. 2019). Instead, Regeneron directed this Court to an older decision where the State of Texas had not intervened and did not participate in the litigation. The parties to the motion to dismiss, including defendant, relator, and the United States, focused "primarily on the FCA" and failed to "argue[] that a different standard applies" to Texas's claims, prompting that court to conduct the same analysis of the federal and Texas claims. *United States ex rel. Carroll v. Planned Parenthood Gulf Coast, Inc.,* 21 F. Supp. 3d 825, 832 n.24 (S.D. Tex. 2014). Such a scenario does not exist here, where the State of Texas has articulated the applicable standard, rendering *Carroll* inapplicable. Because Regeneron does nothing more than misconstrue or ignore the plain language of the TMFPA and recent case law, Regeneron's arguments to dismiss Texas's claims are unavailing.

For the foregoing reasons, and for those reasons stated in the government's Opposition, the Court should deny Regeneron's Motion to Dismiss.

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Respectfully submitted,

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